The Department of Vermont Health Access
Drug Utilization Review Board Policies and Procedures

Mission Statement:

Our mission is to serve beneficiaries, to improve health outcomes, and assure adequate access to safe and effective medication therapy.

Abbreviations:

DUR = Drug Utilization Review
DVHA = The Department of Vermont Health Access
PBM = Pharmacy Benefit Manager
PA = Prior Authorization
PDL = Preferred Drug List
P&T Committee = Pharmacy and Therapeutics Committee
AHS = Agency of Human Services

Purpose:

The Drug Utilization Review Board advises DVHA on its drug coverage policies, clinical criteria for drug use, and reviewing drugs for appropriate utilization, thereby improving the quality of pharmaceutical care provided to members. DVHA manages the publicly funded pharmacy benefit programs for Vermont Medicaid and oversees the activities of the DUR Board. The DUR Board in Vermont serves a dual function, one is the drug utilization review component, whereby the Board applies criteria and standards in the application of DUR activities, reviews and reports the results of DUR activities performed by DVHA, and/or proposes recommended intervention programs such as educational outreach. The second portion of the DUR Board is the P&T Committee role, whereby the board provides guidance on the development of the PDL for DVHA beneficiaries and performs new drug reviews focused on clinical efficacy, safety, and cost. Together these functions result in more clinically appropriate prescribing and savings to Vermont's pharmacy benefit program.

Legislative Authority:

Federal authority for the creation of state DUR Boards was authorized by Congress under Section 4401, 1927(g) of the Omnibus Reconciliation Act of 1990. This act mandated that the Vermont AHS develop a drug use review program for covered outpatient drugs, effective January 1, 1993. This act also required the establishment of a DUR Board which would review and approve drug use criteria and standards for both retrospective and prospective drug utilization review and apply these within the scope DUR activities. The DUR Board also reviews, provides DUR related recommendations for educational intervention programs. State authority is established under the Vermont Statute Title 33, V.S.A 1998, which states that the commissioner of Vermont Health Access shall establish a pharmacy best practices and cost control program designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall include a list of covered outpatient prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives, utilization review procedures, a prior authorization review process and any other cost containment activities adopted by rule by the commissioner. Implementation of this pharmaceutical initiative required that either the DUR Board or a P&T Committee be established to provide guidance on the development of a PDL for Medicaid patients. DVHA elected to

utilize the already established DUR Board as its P&T committee to obtain current clinical advice on the use of pharmaceuticals.

Terms of Membership:
The membership of the DUR Board shall include healthcare professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs
(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs
(iii) Drug use review, evaluation, and intervention
(iv) Medical quality assurance

DUR Board members are required to be Vermont State licensed professionals in good standing. No DUR Board member may have Medicaid or Medicare sanctions against them.

Members of the DUR Board are appointed by the Commissioner of DVHA and approved by the Governor to staggered three-year terms. The Chair shall be elected by vote of the board members. At least one-third, but not more than half, of the Board's membership shall be licensed and actively practicing physicians and at least one-third of the membership shall be licensed and actively practicing pharmacists. The Board may include other qualified individuals as proposed and approved by the Commissioner of DVHA and the Governor. Board members are expected to attend meetings and provide DVHA advanced notice of any excused absences, whenever feasible. Current DUR Board membership can be found on DVHA's website at https://dvha.vermont.gov/advisory-boards/drug-utilization-review-board/durb-members

Members of the Board shall be entitled to compensation in accordance with 32 VSA § 1010 and 32 V.S.A. § 1267, subject to the availability of funding. Current rates can be found at https://humanresources.vermont.gov/compensation/expense-reimbursement

Quorum & Voting
The presence of a majority (≥ 51%) of DUR Board members will be considered a quorum. A simple majority will determine the board's recommendations. Each member may cast 1 vote and the tie will be broken by the DUR Board Chair.

Duties and Responsibilities:
The DUR Board shall carry out the duties and responsibilities required by federal and state law and shall participate in the efforts of DVHA to assure that prescriptions for Medicaid patients are appropriate, medically necessary, and not likely to result in adverse medical events. Specifically, the DUR Board shall:

- Approve any standards utilized in both prospective and retrospective drug utilization review
- Evaluate the results of the application of standards to Medicaid claims data to identify utilization patterns which suggest drug therapy problems
- Determine the content and methodology of specific activities to educate practitioners on common therapy problems
- Provide ongoing educational interventions for practitioners targeted through retrospective review

- Report annually to the Commissioner of the Department of Vermont Health Access concerning the nature and scope of retrospective drug utilization review and educational activity

Prospective Drug Utilization Review

- The DUR Board shall review and make recommendations on predetermined standards submitted to it by DHVA or DVHA's contractor. These standards shall be used by DVHA or DVHA's contractor to screen for potential drug therapy problems due to therapeutic duplication, ingredient duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions, age/condition, and clinical abuse/misuse.
- The DUR Board shall evaluate predetermined standards and make recommendations to DVHA or DVHA's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

Retrospective Drug Utilization Review

- The DUR Board shall review and make recommendations on predetermined standards submitted to it by DHVA or DVHA's contractor. These standards shall be used by DVHA or DVHA's contractor for drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, inappropriate or medically unnecessary care.
- The DUR Board shall evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use and make recommendations to DVHA or DVHA's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

Educational Programs

- The DUR Board shall consider educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.
- The DUR Board shall make recommendations as to which interventions would most effectively lead to improvement in the quality of drug therapy.

Pharmacy and Therapeutics Committee

- The P&T Committee exists to serve DVHA in an advisory capacity for the purpose of developing and maintaining a PDL for Vermont's publicly funded pharmacy programs. This function is a component of the DUR Board. As such, the DUR Board serves as the P&T Committee for DVHA.
- The DUR Board serves as the P&T Committee- 33 V.S.A. § 1998: § 1998. Pharmacy Best Practices and Cost Control Program
- The DUR Board makes recommendations for adoption into the PDL and advises DVHA regarding drugs that may be appropriate for Prior Authorization (PA) due to clinical concerns. The DUR board's recommendations shall be based upon considerations of clinical efficacy, safety, and cost-effectiveness.
- Activities of the DUR Board may include:
    - The review of classes, which should be included on the PDL, being developed and maintained by DVHA

- The review of prescription drugs within classes, which should be included on the PDL
- The review and consideration of clinical analysis provided by DVHA and DVHA's contractor; peer review articles, published judgment regarding diagnosis, conditions, therapeutic considerations and/or medical specialty interests
- Advising DVHA concerning the use of PA for prescription drugs.

- To the extent feasible, the DUR Board shall review all drug classes included in the PDL at least every 24 months and may recommend changes, additions, or deletions in the PDL. (SPA 18-0009, VT-18-0009.pdf (medicaid.gov))
- The DUR Board shall meet at least quarterly.

Conflict of Interest

On an annual basis, members will identify whether they have an association with pharmaceutical manufacturers and will be required to submit an annual conflict of interest disclosure statement to the DUR Coordinator. This should include whether the board member or a family member owns stock in the company (excluding mutual funds), receives honoraria for speaking engagements, monies to support continuing education programs or has been engaged in a research study funded by the company. An appointed committee member who has a financial relationship with a manufacturer shall excuse his/herself from participating in any actions, including discussion, voting, and advising on any issues. Prior to each meeting, board members electronically sign and complete a conflict-of-interest change form or no change form. This form will be used to indicate any changes to the yearly Conflict of Interest questionnaire.

Board members shall not meet with pharmaceutical manufacturers, distributors, retailers, or their representatives in regard to any matters under the review of the DUR Board in order to avoid the appearance of or actual conflicts of interest. A DUR board member shall refrain from discussion or any action on an issue if there is an appearance the board member is conflicted about the topic.

Confidentiality

Sec. 1927. [42 U.S.C. 1396r–8] (b)(3)(D) Information disclosed by manufacturers or wholesalers or under an agreement with the Secretary of Veterans Affairs is confidential and shall not be disclosed by the Secretary, the Secretary of Veterans Affairs, or a State agency (or contractor) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

a. as the Secretary determines to be necessary to carry out this section,
b. to permit the Comptroller General to review the information provided,
c. to permit the Director of the Congressional Budget Office to review the information provided,
d. to States to carry out this title, and
e. to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section 1860D-2(d)(2) (Prescription Drug Benefits) or 1860D-4(c)(2)(E) (Beneficiary Protections for Qualified Prescription Drug coverage) and drug pricing data for drug discount card programs reported to the Secretary of State under the first sentence of section 1860D-31(i)(1).

Net pricing and rebate information is strictly confidential. Board members will remain compliant with this requirement, along with providing a signature attesting to this requirement as part of the conflict-of-interest form.

Code of Ethics Acknowledgement

Each new board member must review and sign the Code of Ethics Acknowledgement, per Executive Order No. 19-17. Signatures must be in print and sent by U.S. mail to the DUR coordinator, who will forward to the Governor's office.

DUR Board Administrative Activities

- Set a schedule for regular meetings
- Publish notices of public meetings
- Prepare and disseminate meeting minutes
- Post agenda to DVHA's website, disseminate DUR materials to board members, expense sheets, Conflict of Interest forms, and Code of Ethics language and signature page.

DUR Board Agenda and Meeting Procedures:

Typically, the DUR Board will meet 7-8 times per year, approximately every six weeks depending on the meeting agendas and content. Annual DUR Board scheduled meetings can be found here: https://dvha.vermont.gov/advisory-boards/drug-utilization-review-board/durb-meeting-schedule-and-location

DVHA works with a Pharmacy Benefits Administrator (PBA) to support select functions of the DUR Board meetings (such as Therapeutic Class Reviews and New Drug Reviews).

Procedure for Regularly Scheduled Meetings:

- Public notice of the time and place of meetings will be provided to the Department of Libraries by the Friday of the week prior to the meeting. This will be published in their calendar of all open meetings conducted by the executive branch. Updates or cancellations may be submitted subsequently.

Meeting Minutes and Agenda:

- The DUR Board meeting agenda is posted on DVHA's website one week prior to the meeting and is available at https://dvha.vermont.gov/advisory-boards/drug-utilization-review-board/durb-agendas
- In accordance with 1 V.S.A. § 312, the minutes of public meetings must be taken and include the names of all members of the public body who attend the meeting, all other active participants, all motions, proposals, and resolutions made, offered and considered, and the disposition of these matters including the results of votes taken. Minutes are public records, which must be available for public inspection within five days of the date of the meeting. Because of the quick turnaround, minutes may not be accepted or approved; these minutes should be labeled as draft or unapproved until they are approved and posted as such. All minutes must be maintained and made available to the public upon request.

Consent Agenda

- The DUR Board agenda may consolidate a number of items to be voted on, without discussion, as a package under a consent agenda. A consent agenda will be posted and included on the full agenda as a topic for the board to vote on.
- The consent agenda differentiates between routine matters not needing explanation and more complex issues needing examination.
- Members of the board are expected to review items distributed on the consent agenda prior to attending DUR Board meetings. Any item that a board member requests to discuss will be removed from the consent agenda and included as a full discussion topic on the full agenda.
- If there is an item on the consent agenda that a member of the public requests to testify about, this item will be removed from the consent agenda and included as a full discussion topic on the full agenda.
- During the DUR Board meeting, the board will vote on approving the consent agenda topics and recommendations.

Executive session

- The DUR Board opens for an executive session in the 30-60 minutes prior to the open meeting, in order to discuss confidential information including rebate agreements and other confidential cost information.
- The information discussed during the DUR Board executive session is confidential. The DUR Committee members will be required to keep all information discussed confidential, which includes all pricing and proprietary information disclosed during the DUR meeting.
- The board may go into executive session in accordance with 1 V.S.A. § 313. To go into executive session the body must affirmatively vote with two-thirds of its members present and must state the reason for the session and limit its consideration to that business. The minutes of the public meeting should reflect the vote concerning both the purpose of the executive session matter and related action and the vote, if any, and other actions taken by the body following executive session.

Public Comment

- In accordance with 1 V.S.A. § 312, at an open meeting, the public shall be given a reasonable opportunity to express its opinion on matters considered by the public body during the meeting, as long as order is maintained. Public comment shall be subject to reasonable rules established by the chairperson.
- In order to give public comment, individuals must submit Vermont's DUR Board – Public Comment Registration Form. This form must be received by the Friday prior to the DUR Board meeting.
- Public comments shall be limited to three minutes per individual. Only one presentation per product will be permitted from representative employed by a pharmaceutical manufacturer.
- Public comments, both written and verbal, will be restricted to products that are being reviewed on the DUR Board meeting's posted agenda.
- The Public Comment Registration Form will be used to describe any disclosures prior to public comment, as necessary.
- Presentations are limited to verbal comments, no visual aids (other than designated handouts) are permitted.

- Presenters will be called for public comment by order of drug review on the agenda.
- Manufacturers and members of the public have the opportunity to present written comments to the DUR Board by directing those comments to DVHA's DUR liaison or delegated representative, as identified on the DUR Board meeting notice.
- All manufacturer and public written comments received and approved by the Friday prior to the DUR Board meeting will be accessible to DUR Board members.
- It is inappropriate for anyone receiving compensation from a pharmaceutical manufacturer to contact a DUR Board member regarding DUR Board agenda items. If a Board member is contacted by anyone receiving compensation from a pharmaceutical manufacturer, no public comment will be allowed on that manufacturer's agenda item during that DUR Board meeting. If a DUR Board member is contacted about an agenda item, it shall be reported to the DUR Director.

Procedure for New Drug Review and Coverage

Drugs may be reviewed during a DUR Board meeting after they have been available in the marketplace for approximately six months. The drugs reviewed must meet CMS' definition of a covered outpatient drug and the manufacturer must have a signed rebate agreement with CMS. Coverage for drugs that have not been reviewed by the DUR Board will be provided based on a case-by-case review process.

Helpful Links and Resources

The Preferred Drug List (pharmacy benefit)
https://dvha.vermont.gov/providers/pharmacy/preferred-drug-list-pdl-clinical-criteria

Fee Schedule (medical benefit)\https://dvha.vermont.gov/providers/codesfee-schedules.

SPA 18-0009 VT-18-0009.pdf (medicaid.gov)

DUR Board Executive Order EO 07-19 - Drug Utilization Review Board.pdf (vermont.gov)